

REMARKS / ARGUMENTS

Status of Claims

Claims 1-64 are pending in the application. Claims 1-64 stand rejected. Applicant has amended Claims 1, 10, 22 and 40, and added new Claims 65-68, leaving Claims 1-68 for consideration upon entry of the present Amendment.

Applicant respectfully submits that the rejections under 35 U.S.C. §101, 35 U.S.C. §102(b), and 35 U.S.C. §103(a), have been traversed, that no new matter has been entered, and that the application is in condition for allowance.

Information Disclosure Statement

The Examiner states “The information disclosure statement filed on 12/20/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.”

Applicant finds in PAIR that the following documents submitted on 12/20/2004 have been classified as “Best Available Copy”, which Applicant presumes are the documents to which the Examiner makes reference: Document #15, EP 1182619 A2 27.02.2002; Document # 17 WO 91/007726 30.05.1991, Document # 18 WO 96/10949 18.04.1996; Document 21 “Advanced Vessel Analysis”; and Document 22 “CardilQ”.

Applicant submits herewith another IDS including legible copies of the above noted documents and requests consideration of the information referred to therein, as the originally filed IDS on 12/20/2004 was in compliance with the provisions of 37 CFR 1.97.

Specification

The disclosure is objected to because of the following informalities: paragraph [0006] contains a typographical error. The Examiner suggests that the word “Tebesian” should be corrected to read “Thebesian”.

Applicant has amended the specification to correct the typographical error. Accordingly, Applicant respectfully submits that the objections of the disclosure informality has been addressed, and requests reconsideration and withdraw of this objection.

Rejections Under 35 U.S.C. §101

Claims 1-39 stand rejected under 35 U.S.C. §101 for being allegedly directed to non-statutory subject matter. The Examiner asserts that the methods described by claims 1-39 do not result in a physical transformation of an object, and they do not provide a useful, concrete, and tangible result.

The Examiner suggests modifying independent Claims 1, 10 and 22 with more descriptive language describing placement of the pacing lead based on the quantification analysis and the 3D model.

Applicant respectfully disagrees that the claims are directed to non-statutory subject matter, as the “useful, concrete and tangible result” is present at least by the 3D model generated from the cardiac acquisition data and the displaying of a cardiac movement profile, which would provide a useful, concrete and tangible to at least the physician.

However, in an effort to advance this case to allowance, and in consideration of other reasons for rejection, Applicant has amended Claims 1, 10 and 22 to now describe a method that includes identifying a site and route for lead placement based on the movement profile and 3D model, determining LV anatomical landmarks and inserting geometric markers into the 3D model, and registering the 3D model with an interventional medical system for visualization of the LV and interventional lead placement thereat. As such, Applicant submits that Claims 1-39 are now even more

directed to a method having a useful, concrete and tangible result, as the placement of biventricular pacing lead on a LV of a patient also has a useful, concrete and tangible result to the patient.

In view of the foregoing, Applicant submits that the claimed invention complies with 35 U.S.C. § 101, and therefore respectfully requests reconsideration and withdrawal of all rejections under 35 U.S.C. § 101.

Rejections Under 35 U.S.C. §102(b)

Claims 1-8 and 40-48 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gerard et al. (Efficient Model-Based Quantification of Left Ventricular Function in 3-D Echocardiography. IEEE Transactions on Medical Imaging. 21(9): pp. 1059-1068. September 2002., hereinafter Gerard).

Applicant traverses this rejection for the following reasons.

Applicant respectfully submits that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, *in a single prior art reference.*” *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Moreover, “[t]he identical invention must be shown in as complete detail as is contained in the *** claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Furthermore, the single source must disclose all of the claimed elements “arranged as in the claim.” *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

Applicant has amended independent Claim 1 to now recite, inter alia:

“...based on said movement profile and said 3D model, identifying a site and a route for biventricular lead placement on the LV;

determining LV anatomical landmarks of interest and inserting geometric markers into said 3D model thereat; and

registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat.”

Applicant has also amended independent Claim 40 to now recite, inter alia:

“...wherein said operator console facilitates identifying a site and a route for biventricular lead placement on the LV, determining LV anatomical landmarks of interest and inserting geometric markers into said 3D model thereat, and registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat.”

Dependent claims inherit all of the limitations of the respective parent claim.

No new matter has been added as antecedent support can be found in the application as originally filed, such as at Paragraphs [0040], [0041] and [0045], and at Figure 2, for example.

In comparing Gerard with the claimed invention as amended, Applicant finds Gerard to disclose 3D Echocardiography for only the functional evaluation of the left ventricle (Abstract), and to be absent on any disclosure of a method that provides interventional procedure planning for interventional lead placement using a 3D model with geometric markers registered with an interventional system. More specifically, Applicant submits that Gerard is absent disclosure of the claimed limitations of: “based on said movement profile and said 3D model, identifying a site and a route for biventricular lead placement on the LV; determining LV anatomical landmarks of interest and inserting geometric markers into said 3D model thereat; and registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat.”

Accordingly, Applicant submits that Gerard does not disclose all of the claimed elements arranged as in the claim, and absent anticipatory disclosure in Gerard of each and every element of the claimed invention arranged as in the claim, Gerard cannot be

anticipatory.

In view of the amendment and foregoing remarks, Applicant submits that Gerard does not disclose each and every element of the claimed invention arranged as claimed and therefore cannot be anticipatory. Accordingly, Applicant respectfully submits that the Examiner's rejection under 35 U.S.C. §102(b) has been traversed, and requests that the Examiner reconsider and withdraw this rejection.

Rejections Under 35 U.S.C. §103(a)

Claim 9 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Gerard.

Claims 10-21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gerard in view of Wahle et al. (3D Heart Vessel Reconstruction from Biplane Angiograms. IEEE Computer Graphics and Applications. 16(1): pp. 65-73. January 1996, hereinafter Wahle).

Claims 22-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard in view of Wahle and further in view of Lattouf (U.S. Publication No. 2003/0120264, hereinafter Lattouf).

Applicant traverses these rejections for the following reasons.

Applicant respectfully submits that the obviousness rejection based on the References is improper as the References fail to teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). The Examiner must meet the burden of establishing that all elements of the invention are taught or suggested in the prior art. MPEP §2143.03. Additionally, Applicant respectfully submits that a prima facie case of obviousness cannot be supported by a proposed modification that would render the prior art invention being modified

unsatisfactory for its intended purpose. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984); MPEP §2143.01.

Regarding Claim 9

Claim 9 is dependent from Claim 1. In view of Applicant's amendment and remarks to Claim 1 as set forth above, Applicant submits that for at least the reason that Claim 9 depends from an allowable claim, Claim 9 is allowable and respectfully requests notice thereof.

Regarding Claims 10-21

Applicant has amended Claim 10 to now recite, inter alia:

“...identifying at least one suitable region on the left ventricle wall for epicardial lead placement based on said determined movement profile and said visualized coronary vessels;

determining LV anatomical landmarks of interest and inserting geometric markers into said 3D model thereat; and

registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat.”

Dependent claims inherit all of the limitations of the parent claim.

No new subject matter has been introduced, as antecedent support may be found in the specification as originally filed, such as at Paragraph [0026], [0040], [0041] and [0045], for example.

The Examiner acknowledges that Gerard does not show visualizing one or more coronary vessels on the generated 3D model and looks to Wahle to cure this deficiency.

The Examiner alleges that Wahle discloses a method of visualizing coronary vessels in 3D for the purpose of planning subsequent treatment (Abstract), that the method of Wahle includes steps for quantifying dimensions of the image blood vessels, and that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Gerard to include the coronary vessel visualization and quantification method of Wahle in order to identify the placement of the coronary vessels

to provide a more comprehensive anatomical model for planning treatment. (Paper 20061031, page 4).

The Examiner further acknowledges that Gerard does not explicitly disclose identifying at least one suitable region on the left ventricle wall for epicardial lead placement, and alleges that it is known in the art that it is desirable to apply left ventricular pacing therapy to the area on the LV that is last to contract during systole in order to optimize cardiac resynchronization. The Examiner then alleges that: “Therefore, identification of the point of last contraction is equivalent to identification of a suitable region for lead placement”, and that since Gerard “discloses identifying the point of last contraction as described above... this limitation is considered inherent to the method of Gerard.” As such, the Examiner alleges that it would have been obvious to one of ordinary skill in the art to use the method of Gerard, modified by Wahle to identify potential regions for epicardial lead placement. (Paper 20061031, pages 4-5).

First, Applicant respectfully disagrees that Gerard in view of Wahle teaches the claimed method of “visualizing one or more coronary vessels *on said generated 3D model*” and “identifying at least one suitable region on the left ventricle wall for epicardial lead placement *based on said determined movement profile and said visualized coronary vessels*”, and submits that the Examiner’s allegation that Wahle discloses visualizing coronary vessels in 3D for the purpose of planning subsequent treatment (Abstract), and that the method of Wahle includes steps for quantifying dimensions of the image blood vessels (Paper 20061031, page 4), falls wholly short of teaching the claimed “visualizing” and “identifying... based on...” limitations.

At page 66, col. 2, last paragraph, Applicant finds Wahle to disclose that “The imaging geometry might not be determined exactly”, at page 67, col. 1, first paragraph, Applicant finds Wahle to teach a precision enhancing algorithm based on interactively set reference points, and at page 68, col. 2, end of first paragraph, Applicant finds Wahle to disclose that “A manual correction of the detected edges is designated”, which Applicant submits is substantially different from the “visualizing” and “identifying... based on...” limitations where the suitable region is identified *based on the determined movement*

profile and the visualized coronary vessels in the 3D model. If Wahle were to be used for such a teaching, one skilled in the art would be left with the question of whether the Wahle method would be suitable for the purpose of the claimed invention since Wahle admittedly lacks determination of exact imaging geometry.

In addition, Applicant finds Wahle to teach that “imaging procedures like CT or MR impose additional costs and do not yet deliver sufficient spatial resolution for coronary artery reconstruction” (page 72, last paragraph), which is entirely contrary to the methodology of the claimed invention.

In view of the foregoing, Applicant submits that Wahle fails to cure the deficiencies of Gerard and provides a teaching contrary to the claimed invention, and therefore fails to teach or suggest each and every element of the claimed invention arranged so as to perform as the claimed invention performs.

Additionally, and in comparing the combination of Gerard and Wahle with the claimed invention as amended, Applicant finds Gerard to teach an “...efficient method for the functional evaluation of the left ventricle from 3-D *echographic sequences.*” (Abstract), and to teach that “*Echocardiography has become a major modality* in the diagnosis of heart diseases *due to its innocuousness, the relatively low cost and small size of equipment compared to other modalities*, and its ability to reveal the anatomy and give functional information in real time.” [Gerard, Introduction, p. 1059, col 1]. Applicant submits that the incorporation of the “...*image intensifiers and the x-ray sources....*” [Wahle, p. 66, col.1] into Gerard to provide “...time equivalent x-ray images from two views” [Wahle, Abstract] as taught by Wahle and suggested by the Examiner would render Gerard *unsatisfactory for its intended purpose (a relatively low cost small equipment size compared to other modalities, to give functional information in real time)*. As such, Applicant submits that there is no motivation to modify Gerard with the teachings of Wahle as alleged by the Examiner, since the resulting modified Gerard would not be an *innocuousness, relatively low cost and small size piece of equipment compared to other modalities.*

Furthermore, Applicant submits that even if Gerard were to be modified by

Wahle, the combination would still be absent each and every element of the claimed invention arranged so as to perform as the claimed invention performs. More specifically, Applicant submits that the combination is still absent:

“...identifying at least one suitable region on the left ventricle wall for epicardial lead placement **based on said determined movement profile and said visualized coronary vessels;**

determining LV anatomical landmarks of interest and inserting geometric markers into said 3D model thereat; and

registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat.”

Applicant submits that the deficiencies of Gerard as set forth in the remarks above with reference to Claim 10 are not cured by Wahle, and for at least this reason Claims 10-21 are directed to allowable subject matter.

Accordingly, Applicant submits that Wahle is absent any teaching, suggestion, or motivation to modify Gerard for the purpose of arriving at the claimed invention while maintaining Gerard to be satisfactory for its intended purpose. As such, Applicant submits that absent a motivation to combine the references as alleged by the Examiner, a prima facie case of obviousness cannot be established.

Regarding Claims 22-64

Applicant has amended Claim 22 to now recite, inter alia:

“...identifying at least one suitable region on the left ventricle wall for epicardial lead placement based on said determined movement profile and said visualized coronary vessels;

...

identifying one or more left ventricle anatomical landmarks on said 3D model and inserting geometric markers into said 3D model thereat;

registering saved views of said 3D model having said inserted geometric markers on an interventional system;

...

identifying a minimally invasive route for epicardial lead placement at said at least one suitable region on the left ventricle wall based on said determined movement profile and said 3D model.”

Applicant has also amended Claim 40 to now recite, inter alia:

“...wherein said operator console facilitates identifying a site and a route for biventricular lead placement on the LV, determining LV anatomical landmarks of interest and inserting geometric markers into said 3D model thereat, and registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat.”

Applicant has further amended Claim 49 to now recite, inter alia:

“...a computed tomography medical imaging system for generating acquisition data”.

In alleging obviousness, the Examiner alleges that Gerard “teaches the use of performing the imaging method with a real-time 3D system from Philips Medical Systems, which *inherently* performs the steps of registering and visualizing saved views of the 3D model, and which is *equivalent to* the interventional system claimed in the instant application (p. 1059, col. 1).” Paper 20061031, page 6 (emphasis added).

Applicant respectfully disagrees that Gerard teaches all that the Examiner alleges Gerard teaches.

For example, Gerard discloses the use of Echocardiography as discussed above. In addition to this disclosure, the Examiner alleges that Gerard *inherently* teaches the claimed steps of registration and visualization to arrive at *an equivalent of* the claimed interventional system. However, in making such an allegation, the Examiner merely references Philip Medical Systems, which is disclosed at p.1059, col. 2 of Gerard. Applicant respectfully disagrees that the mere mention of Philip Medical Systems *inherently* discloses anything, let alone the *inherent disclosure of the claimed registration and interventional system limitations arranged as claimed and to perform as the claimed invention performs*. For an *inherency* argument to stand, the claimed limitation must *necessarily* be present in the prior art reference. Here, the claimed registration involves registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat, which Applicant submits does not *necessarily* exist in Gerard.

In addition, the Examiner looks to Lattouf for curing deficiencies of Gerard and Wahle. More specifically, the Examiner looks to Lattouf for its teaching of “a system and method for implanting an epicardial lead via minithoracotomy... gaining access to the implant site via an opening in the intercostal space between the patient’s ribs.” Paper 20061031, page 7.

Applicant respectfully disagrees that Gerard and Wahle as modified by Lattouf is sufficient to arrive at the claimed invention, and further submits that one skilled in the art would not be motivated to modify Gerard in light of Wahle and Lattouf as such a modification would destroy the intended purpose of Gerard, which as discussed above is to provide *innocuousness, relatively low cost and small size piece of equipment compared to other modalities*.

More specifically, the claimed invention includes at least some of the following limitations:

1. epicardial lead placement based on said determined movement profile and said visualized coronary vessels;

2. identifying one or more left ventricle anatomical landmarks on said 3D model and inserting geometric markers into said 3D model thereat;
3. identifying a minimally invasive route for epicardial lead placement at said at least one suitable region on the left ventricle wall based on said determined movement profile and said 3D model;
4. registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat; and/or
5. a computed tomography medical imaging system for generating acquisition data.

Gerard is directed to the use of 3D Echocardiography, and merely mentions a Philips Medical System Ultrasound, Wahle is directed to the use of image intensifiers and x-ray sources, and Lattouf is applied for its teaching of minithoracotomy. Applicant submits that such a combination of references falls wholly short of teaching each and every element of the claimed invention arranged so as to perform as the claimed invention performs, as the combination of references does not teach the claimed ***lead placement based on the determined movement profile and the visualized coronary vessels***, does not teach the claimed ***insertion of geometric markers into the 3D model***, does not teach ***identifying a minimally invasive route for epicardial lead placement at said at least one suitable region on the left ventricle wall based on said determined movement profile and said 3D model***, does not teach ***registering said 3D model having said geometric markers with an interventional medical system for real-time 3D visualization of the LV and interventional lead placement thereat***. Additionally, the combination of references does not teach all of the above using a ***computed tomography*** imaging system.

In alleging obviousness, the Examiner has not stated with specificity where each and every element of the claimed invention arranged so as to perform as the claimed invention performs may be found in the combination of elements. And, even if the combination of elements were to exist in the references cited, the Examiner has not established a prima facie case of obvious because one skilled in the art would not be

motivated to modify Gerard to arrive at the claimed invention when the purpose of Gerard is to provide an *innocuousness, relatively low cost and small size piece of equipment compared to other modalities*, and the combination alleged by the Examiner would render Gerard unsatisfactory for its intended purpose.

In addition to all of the foregoing, Applicant submits that the claimed invention is directed to a planning procedure for epicardial lead placement, which includes identification of where the lead should be placed and the route to get there, and which takes place prior to an interventional procedure that actually places the lead. Applicant submits that such an arrangement is not disclosed, taught or suggested by the prior art relied upon by the Examiner.

In view of the foregoing, Applicant submits that the References fail to teach or suggest each and every element of the claimed invention and are therefore wholly inadequate in their teaching of the claimed invention as a whole, and fail to teach a modification to prior art that does not render the prior art being modified unsatisfactory for its intended purpose, and therefore cannot properly be used to establish a prima facie case of obviousness. Accordingly, Applicant respectfully requests reconsideration and withdrawal of all rejections under 35 U.S.C. §103(a), which Applicant considers to be traversed.

In light of the foregoing, Applicant respectfully submits that the Examiner's rejections under 35 U.S.C. §101 35 U.S.C. §102(b), and 35 U.S.C. §103(a), have been traversed, and respectfully requests that the Examiner reconsider and withdraw these rejections.

Regarding New Claims 65 - 68

Applicant has added new Claims 65 and 66 that depend from Claims 22 and 49, Claim 67 that depends from Claim 66, and Claim 68 that depends from Claim 1, to now claim previously disclosed but unclaimed subject matter. No new matter has been added

as antecedent support may be found in the application as originally filed, such as at Paragraphs [0030] and [0033], for example.

In view of the amendment and remarks set forth above regarding the allowability of Claims 1, 22 and 49, Applicant submits that new Claims 65-68 are directed to allowable subject matter and respectfully requests entry and notice of allowance thereof.

If a communication with Applicant's Attorneys would assist in advancing this case to allowance, the Examiner is cordially invited to contact the undersigned so that any such issues may be promptly resolved.

Applicant respectfully submits that no fees are due with respect to the IDS submitted herewith, as the originally submitted IDS on 12/20/2004 was in compliance with the provisions of 37 CFR 1.97. However, if any fees are required, the Commissioner is hereby authorized to charge any necessary fees to Deposit Account No. 07-0845.

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, including additional claim fees under 37 CFR 1.16(i), or credit any overpayment, to Deposit Account No. 07-0845.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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